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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,522	03/01/2002	Ulrich Haueter	14347	4086

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INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

NASSER, ROBERT L

ART UNIT PAPER NUMBER

3736

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/087,522	HAUETER ET AL.	
	Examiner	Art Unit	
	Robert L. Nasser	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/8/2002</u> | 6) <input type="checkbox"/> Other: _____ |

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 30, 31, 33, and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Korf et al 6013029. Korf in figure 2 shows a device including an access portion, i.e. subcutaneous interface 2, and an outlet 27 and an inlet 15, where perfusion fluid is circulated through the interface 2 through a fluid channel made up of tubes 13 and 14, from where it picks up components of body fluid, such as glucose. Korf further includes a sensor 3 for detecting the body fluid component. With respect to claim 31, the sensor is removable in that it can be taken out of the device. Claim 33 is rejected in that perfusate flows from the reservoir 6 through the inlet 15, through a supply tube 13 to the discharge tube 14, and eventually out through the outlet 27. Claims 35-37 are rejected in that there is a support plate 12 between the human body and the inlet 15 and the outlet 27.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Korf et al in view of Say 6128519. Say shows the same type of device as Korf et al, where

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there is a check valve 44 for preventing flow of fluid from the sensor back to the needle. Hence, it would have been obvious to modify Korf et al to include such a valve, so as to control the fluid flow and maintain accurate readings. With respect to claim 29, in order to properly work, the reflux valve must be above the plate 26.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Korf et al in view of Pfeiffer et al 5640954. Korf does not show the structure of the interface 2. Pfeiffer et al shows an interface including a membrane surrounding an access portion. As such, it would have been obvious to modify Korf to use such an access device, as it is merely the substitution of one known equivalent structure for another.

Applicant's arguments filed 10/17/2005 have been fully considered but they are not persuasive.

Applicant has asserted that Korf has a membrane placed against the skin and not an "implantable" portion. The examiner agrees that the membrane of Korf is not implanted during use. However, the term "implantable" is an intended use limitation that means only "capable of being implanted." It is the examiner's position that the membrane of Korf is "implantable" and hence Korf meets the claim language.

In addition, Applicant has asserted that Korf does not have an inlet and an outlet. The examiner disagrees, noting that elements 15 and 27 are an inlet and an outlet to the access portion, whether or not they connect to another element, such as a waste or supply reservoir. Hence, there is an inlet and an outlet.

With regard to Korf and Pfeiffer, applicant has asserted that neither reference teaches a sensor in the vicinity of the outlet portion. It is the examiner's position that in figure 2, the sensor 3 is "in the vicinity" of the outlet 27.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (571) 272-4731. The examiner can normally be reached on Mon-Fri, variable hours.

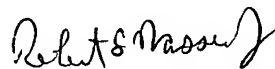
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
January 17, 2006



ROBERT L. NASSER
PRIMARY EXAMINER